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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,958	08/13/2001	Masayoshi Nanba	2519US0P	8993

23115 7590 01/22/2003

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC  
INTELLECTUAL PROPERTY DEPARTMENT  
475 HALF DAY ROAD  
SUITE 500  
LINCOLNSHIRE, IL 60069

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 01/22/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/673,958	<b>Applicant(s)</b> NANBA ET AL.	
	<b>Examiner</b> Brian Whiteman	<b>Art Unit</b> 1635	
	-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on \_\_\_\_.

2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_ is/are objected to.

8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 8/13/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All   b) ☐ Some \* c) ☐ None of:

1) ☒ Certified copies of the priority documents have been received.

2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.

3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input checked="" type="checkbox"/> Other: See <i>Continuation Sheet</i> .
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Continuation of Attachment(s) 6). Other: Notice of non-compliant amendment.

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### DETAILED ACTION

Claims 1-11 are pending examination.

The amendment filed on 8/13/02 has not been entered because it is a non-compliant amendment (37 CFR 1.121).

#### Non-Sequence Compliance

No "SEQ ID NO: " next to sequence(s) in the specification. The sequences are listed in the paper/CD copy. In addition, the paper/CD copy and CRF are correct and entered. However, page 24 of the specification list nucleotide sequences with no SEQ ID NO: (See MPEP 2422.01). In response to this action, these sequences and any other sequences listed in the specification that are not in compliance with sequence rules must be in compliance with M.P.E.P. 2400; 37 C.F.R. 1.821 - 1.825 or the response will be considered non-responsive.

Claims 8-11 will not be considered in the election/restriction because the examiner cannot determine what these claims encompass. Claims 8-11 do not contain steps or materials that would complete the pre-amble of the claims. The phrase "use of the cell culture according to claim 1" does not provide the steps or materials to complete the claims. Claim 9 will not be considered because it is dependent on claim 8. If claims 8-11 are amended in the response to the election/restriction and the examiner can determine what the claims encompass, then the examiner will consider whether the claims are directed to the elected invention or a non-elected invention.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to an immortalized hepatocytes cell culture of human normal cell origin capable of expressing a gene encoding an enzyme involved in the metabolism of xenobiotics in the liver.

Group II, claim(s) 6 and 7, drawn to a method of producing the cell culture according to claim 1 characterized by introduction of the T antigen gene of SV 40 origin into human hepatocytes.

The inventions listed as Groups I-II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-II appears to be that they all relate to an immortalized hepatocyte.

However, US 5,869,243 teaches an immortalized hepatocyte and immortalizing the cells using large T antigen from SV40 DNA.

Therefore the technical feature linking the inventions of groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be an immortalized hepatocytes cell culture of human normal cell origin capable of expressing a gene encoding an enzyme involved in the metabolism of xenobiotics in the liver.

The special technical feature of Group II is considered to a method of producing the cell culture according to claim 1 characterized by introduction of the T antigen gene of SV 40 origin into human hepatocytes.

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Accordingly, Groups I-II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Brian Whiteman

1635

1/15/03

*Scott D. Pribe*

SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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**Notice of Non-Compliant Amendment (37 CFR 1.121)**

The amendment filed on \_\_\_\_\_ is considered non-compliant because it has not been submitted in the format required under 37 CFR 1.121, as amended on September 8, 2000 (see 65 Fed. Reg. 54603, Sept. 8, 2000 and 1238 O.G. 77, Sept. 19, 2000).

- ☒ The amendment does not include a clean version of the replacement paragraph/section. 37 CFR 1.121(b)(1)(ii)
- ☒ The amendment does not include a marked-up version of the replacement paragraph/section 37 CFR 1.121(b)(1)(iii)
- ☐ The amendment does not include a clean version of the amended claim(s). 37 CFR 1.121(c)(1)(i)
- ☐ The amendment does not include a marked-up version of the amended claim(s). 37 CFR 1.121(c)(1)(ii)

**For your convenience, attached to this correspondence is a copy of an informational flyer (MPEP Bookmark Bulletin on "Simplified Amendment Practice").**

Applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to submit an amendment in compliance with 37 CFR 1.121, effective March 1, 2001, in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 C.F.R. 1.136(a).

\_\_\_\_\_  
Legal Instruments Examiner



# Changes to the Patent Rules

October 20, 2000

Volume 1, Issue 3

This is the third in a series of Patent News Bulletins to assist you in keeping up to date with significant rule changes which affect your area. Keep this copy to use as a bookmark for your present MPEP, or view this bulletin again on the USPTO Website.



## Simplified Amendment Practice. Replacement paragraphs/sections/claims to be used. 37 CFR 1.121

The rule package "Changes to the Patent Business Goals - Final Rule," published in the Federal Register on September 8, 2000, 65 Fed. Reg. 54603 (Sept. 8, 2000), and the Official Gazette on September 19, 2000, 1238 Off. Gaz. Pat. Office 77 (September 19, 2000). The PBG rule package makes a number of revisions to Title 37.

The entire final rule may be found at the USPTO Website at <http://www.uspto.gov/web/offices/dcom/olia/pbg/index.html>.

Areas and individuals primarily affected by this rule change include:  
(1) Patent Examiners and Tech Support Staff in the Technology Centers  
(2) Office of Patent Publication

Any questions related to this change in practice should be directed to Joe Narcavage, Special Projects Exr., (703-305-1795) or Liz Dougherty, Legal Advisor, (703-306-3156) OPLA.



Mandatory compliance with the revised rule is not required until March 1, 2001. It is suggested that applicants adopt the revised procedures on or after November 7, 2000, in order to adjust to the changes in amendment practice.

Under the new amendment practice, amendments to the specification must be made by the submission of clean new or replacement paragraph(s), section(s), specification, or claim(s). This practice will provide a specification (including claims) in clean, or substantially clean, form that can be effectively captured and converted by optical character recognition (OCR) scanning during the patent printing process.

The new practice requires applicant to provide, in addition to the clean version of a replacement paragraph/section/claim, a marked-up version using applicant's choice of a conventional marking system to indicate the changes, which will aid the examiner in identifying the changes that have been made. The marked-up version must be based on the previous version and indicate (by markings) how the previous version has been modified to produce the clean version submitted in the current amendment. The term "previous version" means the version of record in the application as originally filed or from a previously entered amendment.

The following format is suggested in an amendment paper: (1) a clean version of each replacement paragraph/section/claim with clear instructions for entry; (2) starting on a separate page, any remarks/arguments (37 CFR 1.111); and (3) starting on a separate page, a marked-up

version entitled "Version with markings to show changes made."

Applicants will also be able to submit a clean set of all pending claims, consolidating all previous versions of pending claims from a series of separate amendments into a single clean version in a single amendment paper. This submission of a clean version of all of the pending claims will be construed as directing the cancellation of all previous versions of any pending claims. No marked-up version will be required to accompany the clean version where no changes other than the consolidation are being made.

The amended rule encourages issuance of applications with an examiner's amendment without practitioners/applicants having to file a formal amendment. Additions or deletions of subject matter in the specification, including the claims, may continue to be

made in an examiner's amendment at the time of allowance by instructions to make any change at a precise location in the specification or the claims. An examiner's amendment may incorporate a printed copy of a fax or e-mail amendment submitted by applicant. Only that part of the e-mail or fax directed to a clean version, or a portion of, a paragraph/claim to be added should be printed and attached to the examiner's amendment, with a paper copy of the entire e-mail or fax being entered in the file. The electronic version of the e-mail is not required to be saved once the printed e-mail (and any attachments) becomes part of the application file record.

*Amendment by  
paragraph/claim  
replacement in clean form.*

MPEP 714+ &amp; 1302.04

MPEP BOOKMARK